DETAILED ACTION

Election Acknowledged

1. Applicants' election without traverse the invention of Group I encompassing claims 36-46 and of the species plasma polymer is acknowledged. The restriction is made final without traverse. Furthermore the species of "plasma polymer" as the material of the transport control layer has been elected.

Status of Application

2. Claims 36-47 are pending, claims 43 and 47 is withdrawn as being directed to nonelected species and/or invention and claims 36-42 and 44-46 are presented for examination on the merits. The following rejections are made.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-42 and 44-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to "an antimicrobial and non-cytotoxic layered material." The claims are considered indefinite because something which is antimicrobial is necessarily cytotoxic (i.e. at least cytotoxic towards microbes). It appears from the specification that the composition is intended to comprise a biocide which is anti-microbial (i.e. cytotoxic towards at least some microbes), but which is non-cytotoxic towards 'higher cells' (i.e. animal cells? eukaryotic cells?) (See specification at page 2, first full paragraph). Applicants should amend the claims so as to more accurately define the selective cytotoxicity of their composition, but should take caution not to introduce new matter.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 36-42, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry (US 7820284; filed 12/3/2001) in view of Vissing et al. (US 7157145; filed 6/28/2002).**

6. Terry teaches microbe-resistant medical devices wherein an antimicrobial substrate is coated with an outer non-antimicrobial polymeric surface. The antimicrobial substrate comprises antimicrobial particles which can be metals and metal salts, oxides and complexes having oligodynamic properties, such as aluminum, antimony, bismuth, cerium, copper, gold, iridium, magnesium, mercury, palladium, platinum, silver, tin and zinc and their salts, oxides, complexes and mixtures thereof (see column 3, lines 60-65; see instant claims 39 and 41). The size of the antimicrobial metallic particles is preferably less than about 3 microns (40 nanometers) (see column 4, lines 1-5; see instant claims 40). The overcoat is to be a polymeric substance which is to be hydrophilic (see column 4, lines 55-60).

7. The medical device of Terry is comparable to the instant claims as follows:

8. Because the medical device comprises at least two substances (i.e. the antimicrobial substrate and the non-antimicrobial polymeric surface) the device is considered to read on a layered material (as required by instant claim 36). The medical device clearly meets the limitation of being 'a medical product' claim 46 as well.

9. The antimicrobial substrate reads on a biocide layer having a biocidal active agent (component a) of claim 36). The species of antimicrobial agents taught by Terry read on those required by claims 39 and 41. The preferred size of the antimicrobial metallic particles (40 nanometers) anticipates the size range required by claim 40.

10. The overcoat is considered to read on a transport control layer covering the biocide layer (component b) of claim 36).

11. The medical device of Terry differs from the instantly claimed invention in that they fail to teach the transport control layer has thickness and porosity adjusted to release an antimicrobial and non-cytotoxic quantity of the biocidal agent from the biocide layer through the transport control layer, nor that the transport control layer is a plasma polymer wherein the transport control layer has a silicon content of 20 to 60%, a carbon content of 10 to 30% and an oxygen content of 30 to 50%.

12. Vissing teaches an article comprising a substrate and a plasma polymer comprising at least 22 to 27% silicon, 25 to 50% oxygen and 25 and 50% carbon wherein the polymer is applied to the surface of the substrate (see abstract; meeting the limitations of instant claims 36 and 42). It's taught that the plasma polymer can be applied to surfaces to impart a smooth and easy to clean surface (see column 2, lines 15-20). The plasma polymer may have a thickness of between 1 nm and 1,000 nm (see column 4, lines 40-45) this range encompasses the claimed range. It has been held that in cases where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. See *In re*

Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). (thereby meeting the limitation of instant claim 45).

13. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teaching device of Terry so as to replace the hydrophilic polymer outercoat with the plasma polymer layer of Vissing for the purpose of imparting the device of Terry with a smooth and easy to clean surface. One would have been motivated to modify the device of Terry so as to replace the hydrophilic polymer outercoat with the surface plasma polymer of Vissing as doing so would impart a smooth and easy to clean surface which is desirable for medical devices. Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results is indicative of obviousness.

14. With respect to the requirement that the transport control layer has a gas permeability for oxygen (O_2) which is preferably in the range from 500 to 700 (cm^3 bar)/(day m^2), this is a property of the polymer having the instantly claimed silicon, oxygen and carbon content. As Vissing teaches a polymer which has silicon, oxygen and carbon content within the range of the instantly claimed, it'd be expected that it too would have overlapping O_2 permeability. Therefore, modification of the medical device of Terry to substitute the hydrophilic polymer outercoat layer with the easy-to-clean plasma polymer layer of Vissing would have been *prima facie* obvious, and the resulting medical product reads on the medical product of instant claims 36-42, 45 and 46.

15. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

16. **Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Terry (US 7820284; filed 12/3/2001) in view of Vissing et al. (US 7157145; filed 6/28/2002) as applied to claims 36-42, 45 and 46 above, and further in view of Burrell et al. (US 6333093; published 12/25/2001).**

17. Terry and Vissing fail to teach the biocide layer has a mean thickness of 5-100 nm.

18. Burrell teaches wound dressings having antimicrobial coatings. The dressing may comprise different layers having antimicrobial activity. Exemplified antimicrobial agents include silver, gold, platinum, copper, bismuth and zing. The thickness of the layer comprising the antimicrobial is to be greater than 60 nm thick (see column 8, lines 40-45; see instant claim 44). Thus, antimicrobial layers having a thickness between 5-100 nm are commonly employed in the art.

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Terry, Vissing and Burrell such that the antimicrobial layer of Terry would possess a thickness of 60 nm with a reasonable expectation in providing a layer suitable for the storage and release of antimicrobial metal particles. One would have been motivated to employ such a thickness as the prior art teaches that such thickness are useful for containing and releasing the antimicrobial active. That is, one would have a reasonable expectation for success in imparting biocidal benefit wherein the structure of Terry and Vissing is modified such that the thickness of the antimicrobial layer is about 60 nm. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
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/Allison M. Ford/
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